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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,607	12/17/2001	Ni Ding	10177-103	5308
20583	7590	12/09/2004	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			LANDREM, KAMRIN R	
			ART UNIT	PAPER NUMBER
			3738	
DATE MAILED: 12/09/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,607

Applicant(s)

DING ET AL.

Examiner

Kamrin R. Landrem

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/14/04 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 6, 9, 10, 11, 12, 17, 20, 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Dayton (USPN 5,449,382).

With reference to Figure 2 Dayton discloses an expandable prefabricated stent 11 that is later coated with a hydrophobic biostable elastomeric material (polyurethane) and a biologically active substance (heparin) (see the Abstract and 3:62-4:18). The coating forms a continuous layer that preserves openings 17. The stent may be formed of stainless steel, nitinol or other appropriate metallic alloy (3:62-4:4).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 4, 7, 8, 13, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Berg (5,464,650).

Dayton, as discussed above discloses the expandable stent for implantation in a patient as claimed. Dayton however fails to disclose the specific thickness and composition of the coating. Berg teaches a self-expanding stent having a coating comprised of a polymer, a solvent, and a therapeutic substance with varying concentrations and a thickness in the range of 50 micrometers to 25 micrometers (see Figure 1 and 2:30-67). The method required for coating the device is extremely simple and allows the manufacturer to control the amount of drug applied to the stent (2:30-67). Berg discloses that the polymer and solvent can be combined in concentrations (mg/L) in Figures 1 and 2 so that the ratio of therapeutic substance to polymer in the solution is dependent of the efficacy of the polymer in securing the therapeutic substance onto the stent and the rate at which the coating is release the therapeutic substance to the tissue and blood vessel (5:8-19). The coating is applied by immersing the stent or coating it with an airbrush, which would require the rotation of the stent to ensure that all sidewalls of the stent are appropriately coated (4:19-35). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the expandable stent

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as disclosed by Dayton by incorporating the coating as taught by Berg to provide a coated stent that is easy to produce and allows the producer to control the thickness and amount of drug that is contained in the coating.

Claims 5 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Berg (5,464,650).

Dayton as modified by Berg discloses the expandable stent for implantation into a patient as claimed. Dayton as modified by Berg does not disclose expressly a coating having a thickness that is about 75 to 200 micrometers. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to coat the device as disclosed by Dayton and Berg with a coating of a different thickness because Applicant has not disclosed that the specific thickness of 75-200 micrometers provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with a coating thickness of 25 to 50 micrometers because this thickness provides the delivery of bioactive substances and maintains a low profile design of the stent. Therefore, it would have been an obvious matter of design choice to modify Dayton and Berg to obtain the invention as specified in claims 5 and 16.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dayton in view of Burton (EP 0565542).

Dayton, as discussed above, discloses the expandable stent for implantation as claimed. Dayton however fails to disclose the specific structure of the stent. It is well known in the art that stents may have various geometries, i.e. parallelograms. With reference to Figure 1 Burton teaches an expandable stent 10 for implantation wherein the openings 22 are substantially in the

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shape of a parallelogram to form a stent with geometry that allows it to expand by itself from a radially compressed condition to a larger diameter that exerts an outward force against the vessel wall to maintain the stent in place (1:5-15 and 2:34-47). Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the stent as disclosed by Dayton in order to produce a stent that is capable of expanding by itself from a radially compressed condition to a larger diameter that contacts the vessel walls and maintains the position of the stent within the patients vasculature.

Response to Arguments

Applicant's arguments with respect to claims 1-22 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamrin R. Landrem whose telephone number is 571-272-4752. The examiner can normally be reached on 8:00-5:00, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kamrin Landrem
Examiner
AU 3738

krl



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